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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,897	08/01/2001	David A. Paslin	17761-704	9677

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EXAMINER	
ROBINSON, HOPE A	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,897	PASLIN, DAVID A.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The preliminary amendment filed on August 1, 2001 has been received and entered.

Specification

2. The disclosure is objected to because of the following informalities:

The specification is objected to because on page 6, the author's names are misspelled in lines 10 and 11 when compared to the spelling provided on page 6 line 24 and 29 (also the period is missing following "et al." on page 6 lines 24 and 29 and extra periods where SEQ ID No. 2 is recited (see SEQ. ID. No.2)). Note that the sequence identifier should be written as "SEQ ID NO:2". The specification is also objected to because the priority document information does not provide the status of the two applications which are now abandoned.

Correction is required.

Abstract

3. The abstract is objected to at line 14 as the word "protein" is misspelled as "proteings".

Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The present application on page 3, refers to the invention as "compositions for treating atopic dermatitis (AD), other atopic diseases and other inflammatory and/or allergic disorders of the skin. Furthermore, the invention relates to a kit which includes the composition. However, the specification provides no laboratory data on experiments done with the composition, no specified dosage to be administered to the patients in the claimed method and no evidence *per se* of the success of the composition in treating atopic dermatitis, other atopic diseases and other inflammatory/allergic disorders of skin. It is disclosed that "applicant observed in his clinical practice of medicine the inhibitory effect of MCV upon

AD" (see page 5) which represents an inadequate written description. The specification provides figures (Figure 4A and 4B) which represents clinically demonstrations of the inhibitory effect of MCV upon a field of AD at a focal distance of 2 and 6 inches. The disclosure does not describe the timing of the pictures taken in terms of a baseline photo before treatment and after treatment results to demonstrate the effect, nor does it give details as to how long it takes to produce the effect showed in the photographs. Figures 5A and 5B illustrates microscopic pictures of a site of AD and the inhibitory effect of MCV on the field of AD in the same patient, however, there's no description of the dosage required to produce that effect or the length of time to achieve that effect. Therefore, the application is devoid of description of utility and working examples of the presently claimed invention.

Additionally, the claimed invention refers to a method wherein the MC148P protein is selected from the group consisting of MC148P1, MC148P2, MC148P3 and fragments, variants, analogs and derivatives of MC148P1, and MC148P3 which possess atopic dermatitis inhibiting activity. Pages 3, 5, 8 and 9 provide a limited discussion of the variants, analogs, derivatives and fragments mentioned above, as it is stated that the fragments, variants etc. have less than a 100% homology which is insufficient description as no characteristics are provided nor any evidence to demonstrate retention of function with regard to inhibitory activity. Furthermore, based on the above discussion the application is absent factual evidence of the effect of MCV on AD as disclosed in the specification. The claimed invention provides a kit with instructions to teach locally delivering the composition to an area adjacent to the atopic

dermatitis, however, it is unclear whether or not instructions will be included on the dosage and length of time as discussed above. Since the specification sets forth no specific details about the composition and method of using the composition based on dosage, the claimed method might not be successful.

Further, the functionality of the protein as subjected to insertional, substitutional or deletion of variants of MC148P which have not been demonstrated (see page 9). The specification also does not describe where in the protein the above alterations will take place. In view of the foregoing, it is apparent that the present application does not provide sufficient guidance/direction to be able to practice the claimed invention commensurate in scope with the claims without undue experimentation.

The figures submitted and applicant's assertion of the effect of the composition on pages 4 and 5 of the specification, may be indicia of a "real world" use, but in view of the absence of disclosure in the application of working examples (i.e. data) and complete details for carrying out the processes indicated and for the use indicated would require further experimentation. Furthermore, the present application does not appear to indicate even what are or are not represented by the alterations that could occur in the protein (i.e., deletions, insertions or substitution). Due to the large quantity of experimentation necessary to determine an activity or property of the disclosed protein and variants, fragments, analogs etc., the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, and the failure of the specification to demonstrate the biological activity for the claimed proteins and fragments, derivatives

etc., undue experimentation would be required of a skilled artisan to make and/or use the claimed invention. Thus, the instant specification lacks adequate written description to demonstrate possession of the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 112, second paragraph, as failing to distinctly point out the subject matter applicant regards as his invention.

Claim 1 is indefinite because the recites "a method comprising" which is open ended and there is no indication of what the "A method" is supposed to be for. Is the dermatitis that which is treated or is it some other disease or condition?

Claims 1, 12 and claims dependent to each are rejected as being indefinite because the claim recites the acronym "MC148P" without providing the spelled out words prior to the first use of the acronym in each independent claim.

Claim 18 is indefinite for the recitation of "and/or" because it is unclear if the slash mark means "and", "or" or "and or", nor is it apparent which term should or is the limiting term in the claim.

Claim 21 is indefinite because the claim recites "includes a he kit".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Karthwohl et al. (PNAS, vol. 94, pages 9875-9880, 1997).

Karthwohl et al. teach a method comprising administering MC148R a protein having the same structure as MC148P of the instant application to patients suffering from atopic dermatitis (claim 1, page 9875). The reference discloses a type 1 and type 2 (claim 2, page 9875). Thus, the reference anticipates the recited "A method...".

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103 (a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Fife et al. (WO 99/09178, February 25, 1999) in view of Untereker et al. (U.S. Patent No. 5,573,503, November 12, 1996).

Fife et al. teach that the only poxvirus that naturally infects humans is Molluscum Contagiosum Virus (MCV) which causes benign proliferative lesions of the skin in normal and immuno-compromised individuals (claim 11). Fife et al. teach that a nucleotide sequence of the MCV genome has permitted the identification of potential candidate viral proteins designated MC148R that may be involved in the escape from the host system. This open reading frame encodes a 104 amino acid protein with significant homology to chemokine-like MCV viral protein in the lesion (see page 4). Further, the reference teaches a method of administering to the individual an inhibitor of chemokine like MCV viral protein activity (claim 1, see page 4). Additionally, Fife et al. teach a method of inhibiting the action of human chemokines in cell, comprising contacting the cells with a composition comprising a chemokine-like MCV viral protein (claim 10, see page 4). There are at least two types of MCV (claim 2, see page 1). There is also provided a method of treating a chemokine mediated disease in a subject comprising a pharmaceutical composition with a vector construct and a pharmaceutically acceptable carrier, excipient or diluent (claims 7-8, see page 5). The pharmaceutical acceptable carriers are described as including any and all solvents, dispersion media, coatings, antibacterial and antifungal agents, isotonic and absorption delaying agents and the like (claims 7-9see pages 72-74).

Fife et al. teach the proteins MC148R1 and MC148R2 as being able to inhibit the action of human chemokines (see page 16). Additionally, Fife et al. teach administration of the compositions via any common route including oral, nasal, buccal, rectal, vaginal or topical (claims 3 and 10). Further, the compounds can be administered parenterally or intraperitoneally or via orthotopic, intradermal, subcutaneous, intramuscular, or intraperitoneal injection (claim 4, see pages 72 and 73). Fife et al. does not expressly teach administering the composition via iontophoresis.

Untereker et al. teach improved methods of ionophoretic drug delivery (claim 5) by intentional selection of drugs with specific characteristics, of iontophoresis device, components or both because this permits an increase in efficiency of drug delivery (see abstract). The reference also teach that the methods and apparatus is used for transdermal medicament delivery (see column 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the claimed invention as a whole based on the above teachings of Fife et al. because Fife et al. teach the same proteins described in the present invention derived from Molluscum Contagiosum Virus and the sequences set forth in the instant application with a 100% sequence identity. Furthermore, Fife et al. teach the same function of the protein in a medicament for skin lesions, the same methods of administering the composition and similar pharmaceutically acceptable carriers. Additionally, an artisan would have been motivated to combine the teachings of Fife et al. and Untereker et al. to arrive at the present invention because Untereker et

al. teach that the ionophoretic drug delivery system utilizing iontophoresis device and components allows for an increase in the efficiency of drug delivery. Thus, the claimed invention was obvious to make and use at the time it was made and was *prima facie* obvious.

8. Claims 12-21 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Fife et al. (WO 99/09178, February 25, 1999) in view of Untereker et al. (U.S. Patent No. 5,573,503, November 12, 1996) and in further view of Fuisz (U.S. Patent No. 5,733,269, March 31, 1998).

The teachings of Fife et al. in view of Untereker et al. as applied to Claims 1-5 and 7-11 are above. Both Fife et al. and Untereker et al. do not teach a kit. Fuisz teach a method and kit for a transdermal drug delivery system useful in treating individuals having maladies requiring topical, subcutaneous, intra-lesional and systemic administration of one or more drugs for a prolonged period of time. Furthermore, the reference teaches a method for employing the present kit to allow self administration including a transdermal delivery system (see abstract and column 1).

In view of the foregoing, it would have been obvious to one of ordinary skill in the art to practice the claimed invention at the time it was made because Fife et al. in view of Untereker et al. teach a method of administering a medicament to an individual topically or transdermally as disclosed in the present application. Furthermore, it is obvious to combine the teachings of Fife et al., Untereker et al. and Fuisz because Fuisz disclose a kit for use in delivering transdermal drugs to individuals. Thus, the

claimed invention was obvious to make and use at the time it was made and was *prima facie* obvious.

Conclusion

9. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

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Hope Robinson, MS

Patent Examiner